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PATENT, TRADEMARK, COPYRIGHT
AND UNFAIR COMPETITION LAW
AND RELATED LITIGATION

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EDWARD B. EVANS 1936-1971

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November 3, 2005

FACSIMILE COVER SHEET

To: Commissioner for Patents
P.O. Box 1450
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Fax: 571-273-8300

From: David E. Jefferies

Re: **Response to Office Action and Amendment**
Application Serial No. 10/047,578
Filed October 26, 2001
PHENYLEPHRINE TANNATE AND PYRILAMINE TANNATE SALTS IN PHARMACEUTICAL COMPOSITIONS
Jeffrey S. Kiel, et al.
Our File: PEDI-04 (formerly KIEL-02)

Pages: 4 (including cover sheet)

MESSAGE/COMMENTS

Failure to do so may result in a subpotent and unmarketable product. The necessity of performing such a calculation decreases the efficiency of the manufacturing process and introduces another possible source of error, which could still result in content variability greater than the claimed composition of the '578 patent.

12) The general cause of increased content variability that is inherently produced in Chopdekar and Gordziel is not difficult to explain. Each step or operation performed in a manufacturing environment introduces some level of variability into the finished product. When the operation in question, such as a method of Chopdekar and Gordziel, involves isolating a tannate salt, such as by beginning with the free-base form and then converting to the tannate salt, and thereafter processing those tannate salts into a composition, the variability is focused on the amount of active ingredient contained in the finished pharmaceutical product. By eliminating the additional isolation step required by the prior art that is a potential source of increased content variability, the compositions as presently claimed are able to provide a consistently better finished product. Thus, by starting with a commonly available salt or free base of the active pharmaceutical ingredient, which is subsequently converted and incorporated in situ as a tannate salt complex, the invention provides an efficient and reproducible method to manufacture liquid or semi-solid products containing tannate salt complexes as active ingredients.

13) The decreased content variability that results in the claimed compositions due to the recited method has many real world advantages. A better-finished product in the pharmaceutical industry means a safer drug. The principal properties affected by converting a drug to the tannate salt form is solubility, which normally decreases after conversion to a tannate from a hydrochloride salt or bromide salt. The decreased solubility attained in this matter gives the drug prolonged action characteristics. Changes in the content of the tannate salt in a final drug product can potentially alter the overall amount of drug taken, as well as the rate at which the drug enters the body. Understandably, then, increased variability in drug content leads to increased risk to the patient taking the drug product. The need for increased safety and content uniformity is multiplied by the fact that many of the tannate drug products are designed for use by children.

14) I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Application Serial No. 10/047,578
Declaration under 37 CFR § 1.1.32
Reply to Office Action dated May 4, 2005

Further Declarant sayeth naught.

11/24/05
Date

H. Greg Thomas